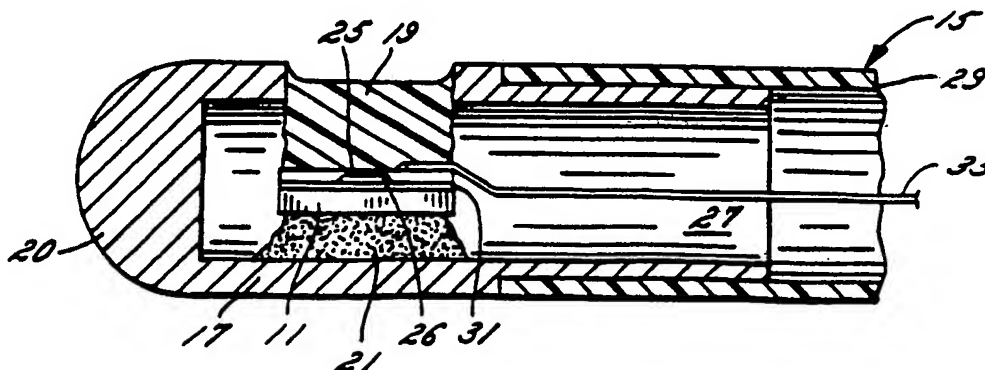


PCTWORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁵ : A61B 5/0215	A1	(11) International Publication Number: WO 90/06723 (43) International Publication Date: 28 June 1990 (28.06.90)
(21) International Application Number: PCT/US89/05586 (22) International Filing Date: 19 December 1989 (19.12.89) (30) Priority data: 287,844 21 December 1988 (21.12.88) US (71) Applicant: ENDOSONICS CORPORATION [US/US]; 3078-B Prospect Park Drive, Rancho Cordova, CA 95670 (US). (72) Inventors: ROSE, Luke, E. ; 64 Grand Rio Circle, Sacramento, CA 95826 (US). MARSH, Wilbert, I., Jr. ; 9324 Rolling Acres Court, Orangevale, CA 95662 (US).		(74) Agent: CONKLIN, John, B.; Leydig, Voit & Mayer, One IBM Plaza, Suite 4600, Chicago, IL 60611 (US). (81) Designated States: AT (European patent), BE (European patent), CH (European patent), DE (European patent), ES (European patent), FR (European patent), GB (European patent), IT (European patent), JP, LU (European patent), NL (European patent), SE (European patent). Published <i>With international search report.</i>

(54) Title: APPARATUS AND METHOD FOR SENSING INTRAVASCULAR PRESSURE**(57) Abstract**

A pressure sensor assembly (11) is provided for placement within the tip of a conventional catheter (15) or the like for insertion into a small cavity such as a human coronary artery. The pressure sensor assembly (11) is comprised of device and backing dies (67 and 75) of crystalline material bonded together without the use of a bonding material, thereby providing direct contact between the two crystalline dies. A diaphragm (25) is etched into one of the dies before it is bonded to the other die. A cavity (26) formed by the diaphragm when the two dies are bonded is vented to a reference atmosphere by a channel or groove (31) in the backing die. During the fabrication of the sensor assembly, small holes (71) are etched completely through the wafer (75) used to form the device dies in order to provide targets for alignment during the fabrication of the sensor assembly. Finally, the fabrication of circuitry on the wafer forming the device dies includes providing complementary temperature coefficients of the nominal piezoresistance and of the piezoresistive coefficient.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	ES	Spain	MG	Madagascar
AU	Australia	FI	Finland	ML	Mali
BB	Barbados	FR	France	MR	Mauritania
BE	Belgium	GA	Gabon	MW	Malawi
BF	Burkina Faso	GB	United Kingdom	NL	Netherlands
BG	Bulgaria	HU	Hungary	NO	Norway
BJ	Benin	IT	Italy	RO	Romania
BR	Brazil	JP	Japan	SD	Sudan
CA	Canada	KP	Democratic People's Republic of Korea	SE	Sweden
CF	Central African Republic	KR	Republic of Korea	SN	Senegal
CG	Congo	LI	Licchtenstein	SU	Soviet Union
CH	Switzerland	LK	Sri Lanka	TD	Chad
CM	Cameroon	LU	Luxembourg	TG	Togo
DE	Germany, Federal Republic of	MC	Monaco	US	United States of America
DK	Denmark				

APPARATUS AND METHOD FOR SENSING INTRAVASCULAR PRESSURE

TECHNICAL FIELD

The invention generally relates to the measuring of pressure utilizing a catheter equipped with a pressure sensing apparatus and, more particularly, to the recording of physiological pressure for vascular application, such as peripheral blood vessels, chambers of the heart and coronary arteries, and non-vascular applications, such as intrauterine or intracranial pressures and the like.

BACKGROUND OF THE INVENTION

Very accurate, distortion-free recordings of blood pressure waveforms are often required in many critical care or interventional clinical situations. This is typically done through the use of a saline-filled catheter, the distal end of which is located at the measurement site. Outside the body, the proximal end of the catheter is connected to an external pressure transducer. The pressure in the vessel is transmitted via the fluid column, detected by the transducer and displayed by suitable electronic means. For example, the precise measurement of haemodynamic pressures can be an important adjunct to surgical procedures such as angioplasty. It is known that the differential blood pressure across a lesion, known as the pressure gradient, can be correlated to successful treatment. Typically, the aim is to reduce the pressure gradient to a minimally acceptable value, implying that the lesion has been dilated to an acceptable level, and minimizing the need to repeat the procedure. The current technique utilizes the guidewire lumen of a balloon catheter to communicate the intravascular pressure to a pressure transducer located outside the body.

Several problems are known to exist with the external transducer technique. For example, the fluid column may not give a true transmission of the waveform due to the damping or ringing within the tube. The possibility of introducing air into the vasculature exists which, of course, is potentially dangerous. The catheter itself can obstruct the flow of blood due to its size relative to small vessel lumen. Many balloon catheters cannot be used to make pressure measurements since their lumens are too small to yield satisfactory results.

As a group, these type of pressure sensors are typically referred to as external fluid-column transducers and are presently in common use. In addition to the foregoing limitations, this type of transducer has significant additional limitations which makes it less than completely satisfactory for use in patient monitoring, particularly critical care situations. For example, the set-up of the catheter is difficult and time consuming. Because of the fluid column, there is a potential for patient contamination. Also distortion in the pressure reading may result from motion artifacts, kinking in the catheter line or air bubbles present in the system. All of the foregoing limitations are directly or indirectly related to the fluid column which propagates the pressure sensed at the tip of the catheter to the external pressure transducer.

A second type of pressure sensing device, which may be fitted to the distal end of a catheter, is a semiconductor device which senses stress of a semiconductor crystal structure in response to the pressure of the ambient environment. The semiconductor material includes piezoresistive elements which respond to the stress by changing electrical

resistance to current flow. This resulting electrical signal can be detected by an external measuring device via wires threaded through the catheter. There is, therefore, no need for a fluid column as a transmission medium.

These catheter tip pressure sensing devices have many advantages over the fluid-column devices. For example, the set-up is simpler and less time consuming. The risk of contamination is substantially less, and the risk of introducing an air bolus into the patient is eliminated. Finally, since the pressure waveform is transduced at the site of measurement, its electrical representation is distortion free.

Unfortunately, the semiconductor pressure sensors which fit on the tip of a catheter are relatively fragile and expensive. Also, they are not available in small sizes for use in measuring pressure in small cavities such as coronary arteries. In this connection, they are usually of such large sizes that an extra lumen for a guide wire cannot be provided. Moreover, the catheter tip pressure sensors may require special interface circuits at the proximal end of the catheter in order to match the transducer output with standard monitoring devices.

SUMMARY OF THE INVENTION

It is a primary object of the invention to provide a semiconductor-based pressure transducer which is small enough to be encapsulated within a catheter for insertion into very small body cavities such as the coronary arteries. In this connection, it is an object of the invention to provide a semiconductor sensor which can be fitted to the distal

end of a catheter while maintaining room for an extra lumen for purposes such as the insertion of a guidewire, sampling of body fluids and the like.

It is a related object of the present invention to produce a semiconductor pressure transducer device meeting the foregoing size requirements which has a structural integrity sufficient to withstand the stresses produced by movement of the catheter when in its in vivo position.

Another object of the invention is to provide a device having the foregoing qualities which has a substantially constant sensitivity to pressure throughout the biological temperature range. In this connection, it is a related object of the present invention that the transducer device has a substantially linear response to pressure throughout the biological temperature range.

Another object of the present invention is to provide a pressure sensitive transducer device which is electrically compatible with standard medical display devices or recording equipment. More particularly, it is an object of the present invention to provide a transducer device which does not require additional amplification or processing equipment in order to interface with the standard medical monitoring devices.

It is another object of the invention to provide a pressure sensitive transducer device which is of sufficiently low cost that the device is essentially disposable.

It is still another object of the present invention to provide a transducer device which exhibits substantially distortion-free frequency response through the physiological range.

Other objects and advantages of the invention will be apparent from the following summary and detailed description and the accompanying drawings.

The invention utilizes a unique process for forming a miniaturized semiconductor pressure transducer. In connection with the process for making the miniature transducer of the invention, several design criteria have been identified which complement the unique process in order to minimize the sensor die size. Other novel design features of the sensor maintain a desired performance level at these reduced dimensions. As currently fabricated, the length, width and thickness of the die is .040 inches by .020 inches by .011 inches, respectively. However, the design and fabrication procedures of the invention can also be used to produce smaller devices. In accordance with the invention, a number of silicon wafer fabrication techniques are combined in a particular, unique sequence in order to achieve the small die size for the pressure sensing transducer. In addition, there are specific novel design features of the sensor which allow it to achieve a desired performance level within catheters.

As is known in the art, semiconductor pressure sensors are typically fabricated by etching a thin diaphragm from a portion of a silicon die so that the diaphragm flexes slightly upon application of a stress. From two to four piezoresistive elements are then implanted into the surface of the diaphragm, oriented to particular crystal axes and configured as a half or full bridge circuit. When stress is applied, the resistors change electrical characteristics (the piezoresistive effect) to a sufficient degree that the bridge imbalance can be detected in response to an applied voltage or

current. With proper design, the piezoresistive effect can be made linear over a given range of stresses. The piezoresistive effect is most pronounced in silicon of a $\langle 100 \rangle$ crystal orientation, hence this is the material of choice for the wafer from which the die is formed.

The critical design consideration which determines how small the sensor die can be made is the minimum dimension diaphragm which can be realized for a given wafer thickness while maintaining a structurally adequate rim of thick silicon around the diaphragm. In order to etch a diaphragm into a silicon wafer of $\langle 100 \rangle$ crystal orientation, an anisotropic etchant must be used which produces a thinning of the wafer along $\langle 111 \rangle$ crystal planes at an angle of 54.7° to the surface. The ratio of the thickness of the diaphragm to that of its length should be 1:60 or more in order to achieve sufficient flexibility. Since there must also be a suitable border of thick silicon remaining for structural integrity of the die, the thickness of the wafer becomes the limiting factor in determining die size.

Sufficient thickness of the wafer is required to ensure that the wafer does not shatter during processing. In conventional wafer fabrication technology, wafers with a thickness of .012 to .015 inches or more are used to minimize breakage. For pressure sensors, this limits the minimum die size possible due to the etch angle constraint explained above such that only large die can be realized which are not suited for small catheters. As an example, for a .015-inch thick wafer, in order to produce a die with a diaphragm of length .010 inches, a die of width .037 inches is required, allowing a thick silicon edge of .003 inches. In the

present invention, the same diaphragm length of .010 inches can be realized in a die of .020 inch width with the same .003 inch thick silicon edge.

In conventional processing, the circuitry is fabricated first onto the wafer and the last step of the process involves etching the diaphragm. In the conventional sequence, a thick wafer must be used in order to accommodate all of the high temperature and cleaning steps required to fabricate the circuitry.

In contrast to the conventional approach, the fabrication process of the invention provides for the etching of a diaphragm into a thin wafer prior to the fabrication of the circuitry onto the wafer. After the diaphragm is etched, the thin wafer is bonded to a thicker wafer in order to provide the mechanical support necessary for the other processing steps such as circuit fabrication. The method of bonding the two wafers is a critical step for proper functioning of the pressure sensing device of the invention. If the bonding of the wafer is done using a dissimilar material (e.g., silicon dioxide or glass), different temperature coefficients of expansion of the materials will cause poor operation of the device at different temperatures due to differential stresses. In the present invention, a thin silicon wafer is bonded directly to a thicker silicon wafer without a third material as a bonding agent. This is done by thorough cleaning of the surfaces under class 10 or better clean room conditions followed by a heat treatment. In accordance with this method, no temperature-induced stresses occur since dissimilar materials are not introduced at an interface between the two wafers. Subsequent to the bonding of the two wafers, the other process steps required to fabricate the electronic circuitry are performed.

In forming the diaphragm on the thin wafer, a critical parameter which must be controlled is the thickness of the diaphragm. If the thickness varies between dice, a variation in the sensitivity of each die results, thereby decreasing the ability to produce a low-cost standard device. Several methods of thickness control are well known, and for the precise control of diaphragm thickness, the method of electrochemical etch stopping is believed by applicants to be the best technique, and is accordingly a preferred method for this invention. To applicants' knowledge, this method has not been applied to produce diaphragms as thin (e.g., 3-4 microns) as are required in the present invention. As set forth hereinafter, applicants have modified the conventional method of electrochemical etch stopping to include a particular process of wafer preparation and a special purpose fixture to ensure that the proper electrical bias parameters are present on the wafer surface during the etching procedure. Failure to provide these conditions results in a premature etch stop in a diaphragm which is too thick or non-uniformly etched.

The net pressure detected by a sensor is the difference between the pressures on the two sides of the diaphragm. In the present invention, one side of the diaphragm is vented to the atmosphere, and it is typically called the reference side. In prior art devices, since the diaphragm is etched as the last step in fabrication, the entire back surface of the diaphragm is open for venting to the atmosphere. When the die is subsequently mounted to a backing plate (usually of amorphous glass or metal), a hole is drilled through the backing plate as a vent. In the present invention, however, the wafer which has

been etched to form a diaphragm and the backing or support wafer are bonded in an early step of the fabrication. A reference channel which vents the reference side of the diaphragm to atmosphere is provided in a novel manner by chemically etching a groove into the surface of the backing wafer along the length axes of the wafer. When the thin wafer containing the diaphragm is bonded to the support or backing wafer, the groove forms a channel through the die which communicates the reference side of the diaphragm to the atmosphere surrounding the die. During encapsulation of the die in a catheter, the vent provides a means for communicating atmospheric pressure from the outside of the patient's body through a connector affixed to the proximal end of the catheter to the reference side of the diaphragm.

Normal process tolerances during fabrication of the piezoresistors on the diaphragm result in different nominal values for the resistors. Upon excitation of the bridge network formed by the piezoresistors, the slight difference in nominal values produces an unstressed offset which must be reduced to an acceptable value. In accordance with the invention, the offset reduction is accomplished on-board the die by including in one arm of the bridge network a resistor trim ladder network. This resistor trim ladder network is a thin film network which is deposited by conventional metal sputtering. Each element of the resistor trim ladder is accessible electronically through a contact pad so that any combination of resistor values up to a defined maximum may be trimmed into the bridge circuit in order to zero the unstressed offset value. Alternatively, the resistor trim ladder may be adjusted by means of a laser beam.

Each piezoresistor has a temperature coefficient of resistance (TCR) which defines the amount of change in resistance of piezoresistors with respect to temperature at a constant pressure. As discussed more fully hereinafter, the four piezoresistors are fabricated so as to have nearly the same TCR values. Therefore, if the piezoresistors are closely matched, they will each vary in response to temperature changes by approximately the same amount. In the balanced bridge network, the changes in resistance in response to temperature will effectively cancel, thereby maintaining a zero unstressed offset value. However, if the thin film network has a different TCR value, errors will be introduced in response to temperature fluctuations.

In accordance with another aspect of the present invention, the TCR value of the piezoresistors is matched to the TCR value of the alloy chosen for the thin film trim network. By matching these TCR values, the trim network may be used to successfully balance the bridge network during calibration and will thereafter maintain the balance in response to temperature variations. In the preferred embodiment, the temperature variation range is between 15 and 40° Centigrade, since this is the temperature range between the normal ambient environment surrounding a patient and the patient's body temperature.

For a given diaphragm geometry and resistor placement, the magnitude of the voltage output of the bridge network is a function of temperature and pressure, and is dependent on the TCR value of the piezoresistors, the temperature coefficient of the piezoresistive coefficient of the piezoresistors (TCPI) and external span resistors (if any). The TCPI means that the sensitivity of the bridge to

pressure changes is a function of temperature. The TCR of the piezoresistors will cause resistance of the bridge network to increase with temperature. By placing the sensor in series with external span resistors that have a TCR of zero, the voltage drop across the bridge network changes in response to changes in ambient temperature. Although the sensitivity of the network may have been altered by the TCPI in response to a change in temperature, the change in the voltage drop across the bridge network caused by the TCR serves to maintain the same output magnitudes for given pressure differentials across the diaphragm. By careful application of conventional design techniques, the TCR values of the piezoresistors can be made to offset their TCPI values for certain values of resistors located off-chip. In other words, when a temperature change occurs, the TCR of the piezoresistors will increase/decrease the magnitude of the signal from the bridge network by an amount equal to the decrease/increase caused by the TCPI.

In the present invention, the doping of the piezoresistors is chosen to maximize piezoresistive coefficients and to minimize the piezoresistive sensitivity to small changes in the doping level, thereby assuring uniformity among different transducers.

Since the transducer of the invention is intended to be incorporated into the distal end of a catheter, power dissipation on the chip is an important consideration. Not only should the temperature of the catheter tip remain within physiological limits, but performance of the device is enhanced by minimizing self-heating of the chip because of the temperature considerations discussed

above. An off-chip resistor network located in the electrical connector joining the proximal end of the catheter to the standard measuring equipment dissipates much of the power at an external location, thereby minimizing self-heating.

Additionally, only the relatively small off-chip resistors are required to create a standardized output that may be directly inputted to industry standard pressure monitors without requiring an interface device housed in a bulky box and inserted between the catheter output receptacle and the input to the monitors. To achieve the goal of matching the output signal to standard pressure monitors in a batch fabrication environment, the sensor is designed to produce a nominally greater sensitivity than expected by commercial monitors. The off-chip resistor network is located in the receptacle or electrical connector outside of the body and at the proximal end of the catheter for use in reducing the sensitivity of the pressure signal to a standardized output specification.

Once the die and its associated electronics have been fabricated, the die is encapsulated within the distal end of a catheter. The material used to encapsulate the die should be a medical grade silicone or material with similar properties. In one of the illustrated embodiments, the catheter is a dual lumen design having a nominal wall thickness of .005 inches. One lumen is dedicated to the encapsulation of the die, and the second lumen is open and large enough for fluid sampling or injection, die injection, external pressure monitoring or guidewire passage. The sensor lumen extends beyond the guidewire lumen so that the sensor may be mounted with the diaphragm centered under a

hole located in the flat center wall of the lumen which faces the guidewire lumen. This feature allows the sensor to measure pressure without the possibility of being wedged against a vessel wall. Side facing pressure measurement also eliminates the erroneous inclusion in the pressure reading of the kinetic energy term of the flowing blood.

During encapsulation, the reference pressure V-groove which communicates the reference side of the diaphragm to atmosphere is kept open and clear by temporarily inserting a wire into the groove. The wire is later retracted after the encapsulant is cured. Atmospheric pressure is communicated to the reference side of the diaphragm by way of the groove and a hole in the electrical connector joining the electrical lumen of the catheter to the monitoring equipment.

The encapsulant material is chosen such that it does not bond to the die but envelopes it so that stresses applied to the catheter tip are effectively absorbed by the encapsulant, thereby minimizing stress on the die.

The thickness of the encapsulant over the diaphragm can be uniformly controlled to eliminate waveform distortion of the pressure transmitted through the encapsulant to the diaphragm. The encapsulant over the diaphragm serves to provide electrical and environmental isolation between the die and the interior of the cavity under examination -- e.g., a blood vessel. To eliminate the transmission to the sensor of stresses due to catheter flexing, the sensor may be surrounded by a suitable rigid support, such as may be fabricated from stainless steel tubing ground into a half-round shape. This piece may be inserted into the catheter

lumen so as to provide a rigid support member around the sensor.

BRIEF DESCRIPTION OF THE DRAWINGS

While the invention will be described in connection with the preferred embodiments, it will be understood that it is not intended to limit the invention to a particular embodiment. On the contrary, it is intended to cover all alternatives and equivalents as may be included within the spirit and scope of the invention as defined by the appended claims.

FIG. 1 is a magnified perspective view of a sensor incorporating the invention, illustrating the size of the sensor relative to a U.S. 10 cent coin;

FIG. 2(a) is a magnified plan view of the tip of a conventional catheter incorporating the sensor of FIG. 1;

FIG. 2(b) is a cross-sectional view of the catheter and sensor of FIG. 2(a) taken along the line 2b-2b;

FIG. 2(c) is a cross-sectional view of the catheter and sensor of FIG. 2(a) taken along the line 2c-2c;

FIG. 3(a) is a magnified plan view of the tip of a conventional catheter with a lumen for a guidewire incorporating the sensor of FIG. 1;

FIG. 3(b) is a cross-sectional view of the catheter and sensor of FIG. 3(a) taken along the line 3b-3b;

FIG. 3(c) is a cross-sectional view of the catheter and sensor of FIG. 3(a) taken along the line 3c-3c;

FIG. 4 is a schematic diagram of a pressure sensor monitoring system incorporating a pressure sensor according to the invention;

FIG. 5 is a process flow diagram depicting the basic processing steps and the sequencing necessary to produce a set of pressure sensors according to the invention;

FIG. 6 is a plan view of a device wafer illustrating a plurality of diaphragms and sets of target holes used for alignment purposes in accordance with the invention;

FIG. 7 is a plan view of a backing wafer showing a pattern of grooves according to the invention;

FIG. 8 is a side view of the device and backing wafers of FIGS 6 and 7, respectively, taken along the lines 8-8 and showing etched targets, diaphragms, and grooves in proper relative alignment;

FIG. 9 is a magnified perspective view showing a sensor assembly with its device and backing dies separated;

FIG. 10 is a plan view of the surface of the device die illustrating the contacts, leads, and trim network which comprise the sensor;

FIG. 11 is a schematic diagram of the pressure sensor circuit; and

FIG. 12 is a side view of a pair of bonded dies for a sensor assembly according to an alternative embodiment of the invention wherein each of the two bonded dies serves both as a device and as a backing for the other die.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Turning to the drawings and referring first to FIG. 1, a sensor assembly 11 of an extremely small size is fabricated to function as a pressure sensor. To provide some appreciation for the small size of the die, a portion of a U.S. coin 13 of a 10 cent denomination (dime) is shown beside the

sensor assembly 11 in the same scale. Pressure sensors of such small size may be mounted to catheters or other suitable means (such as guidewires). Vascular applications of the sensor assembly 11 which are not served well by prior art devices include entry into very small cavities, such as adult coronary arteries or pediatric vessels, or less traumatic entry into larger cavities, such as heart chambers or peripheral vessels. Non-vascular applications of the sensor assembly 11 include intracranial and various gastrointestinal and urological pressures. In general, a very small sensor-tipped catheter may be utilized advantageously wherever pressure waveform accuracy, patient safety, or inaccessibility by other techniques is a significant issue.

Exemplary embodiments of the sensor assembly in a catheter are illustrated in FIGS. 2 and 3. Referring first to the preferred embodiment of FIGS. 2(a), (b) and (c), the sensor assembly 11 of Fig. 1 is mounted in a conventional catheter 15 suitable for cardiovascular or other critical care pressure monitoring, such as of size 2.5 to 4 French. The sensor assembly 11 is supported in the catheter 15 in such a manner that the sensor is sensitive to changes in the pressure within the vessel (not shown), while insensitive to external stresses imposed upon the catheter, such as from vessel movement, and yet the sensor assembly is protected from the environment of the blood or other body fluid. This type of support may be accomplished by proper design of a rigid sensor carrier 17 and use of suitable encapsulation material 19.

Specifically, the sensor assembly 11 is secured by adhesive 21 inside the cylindrically-shaped

carrier 15 which is inserted into the end of the catheter 17. The carrier 17 may be formed from stainless steel, ceramic, or other suitable material. In general, the wall thickness of the carrier 17 must be sufficient so that mechanical stresses from insertion, catheter or vessel flexing, or other sources are not transmitted to the sensor assembly 11. A window 23 is provided in the carrier 17 so that a pressure-sensitive diaphragm 25 of the sensor assembly 11 (formed by a cavity 26 in the assembly) may communicate with the fluid surrounding the catheter. Encapsulation material 19 is a pressure coupling medium (e.g., an RTV silicone) which allows for high fidelity transmission of pressure variations to the sensor assembly 11 yet provides environmental and electrical isolation of the sensor from ambient body fluids. Catheter tip 20 is of rigid design and may be fabricated as an integral part of carrier 17. Alternatively, catheter tip 20 may be formed from various well-known epoxies or other fluid impermeable materials. Tip 20 functions to present a smooth, bio-compatible finish and moisture seal to the catheter interior. A reference pressure cavity 26 of the sensor assembly 11 communicates with an inner lumen 29 of the catheter 15 through a bore 31 which extends through the length of the sensor assembly 11 and through lumen 27 of carrier 17. The inner lumen 29 is vented to room air pressure through a port in an electrical connector (not shown in FIGS. 2a-2c) at the proximal end of the catheter. Electrical connection to the sensor assembly 11 is made via a four-wire cable 33 bonded to pads (not shown in FIGS. 2(a)-2(c)).

In the alternative packaging embodiment of FIGS. 3(a)-3(c), the sensor assembly 11 of FIG. 1 is contained within the lumen 35 of a double lumen catheter 37. A second lumen 39 is available for passage of a guidewire 41, such as would be used to assist in placing the catheter 37 into a desired location within a small vessel or in passing through a cardiac valve or stenotic area. The lumen 39 may also be used for sampling of blood or direct infusion into the bloodstream. To reduce stress, the sensor assembly 11 is secured to a rigid carrier 43 which functions in a manner similar to carrier 17 of FIGS. 2a-2c and which may be fabricated from the same types of materials. As with the embodiment of FIGS. 2a-2c, a window 45 is provided to allow transmission of pressure variations through a pressure coupling medium 47 to the diaphragm 25 of the sensor 11. The material comprising the pressure coupling medium 47 may be the same as that of the coupling medium 19 of the FIGS. 2a-2c embodiment. A catheter tip 49 provides a function similar to that of the catheter tip 20 of FIG. 2(c). Reference pressure to the sensor assembly 11 is provided to the V-shaped bore 31 through inner lumen 35 which is vented to room air pressure through a port in an electrical connector (not shown). As with the embodiment of FIGS. 2(a)-2(c), the electrical connection to diagnostic equipment is made via four-wire cable 33 bonded to pads (not shown) on the sensor assembly 11.

A pressure sensor catheter such as that of FIGS. 2 or 3 may be incorporated into a pressure monitoring system for use in an intensive care unit. In FIG. 4, a standard monitor 53 includes a source 53a for excitation of the sensor 11 and a meter 53b for displaying a pressure signal. An

electrical connector 55 contains a compensation network 57 and serves to communicate excitation signals from the source 53a to the pressure sensor assembly 11 and pressure signals from the sensor to the meter 53b via lines 33. The network 57 attenuates the pressure signals from the sensor assembly 11 so they are of a standard sensitivity and capable of direct transfer to the standard monitor 53. As explained more fully hereinafter, the network 57 also functions to compensate the pressure signals for pressure offset and changes in ambient temperature, which cannot be compensated using only the on-chip techniques provided by the invention. As illustrated in FIG. 4, the sensor assembly 11 includes a Wheatstone bridge integrated circuit comprising piezoresistors R_1 , R_2 , R_3 and R_4 and a trim network 61. The trim network 61 provides an offset adjustment for the bridge circuit, as well as limited temperature compensation. As described more fully hereinafter, the trim network 61 consists of a thin film resistor ladder of metal chosen to have a temperature coefficient of resistance (TCR) comparable to the TCR of the piezoresistors R_1 - R_4 .

Pressure sensor assemblies fabricated in accordance with the invention utilize the piezoresistive effect for sensing strain in the silicon lattice of a diaphragm formed in the die comprising the sensor, and this effect is most pronounced in <100> silicon. In addition, formation of the thin diaphragm in crystalline silicon is achieved by selective chemical etching (thinning) of a defined area of the die to a specified depth, with uniform sidewall geometry. For this operation, <100> silicon is also the material of choice. In the prior art, pressure sensors are typically fabricated from a

single silicon wafer. In this connection, conventional fabrication processes require a sufficiently thick wafer such that structural integrity is maintained during the processing steps; typically a .012 - .015 inches or thicker wafer is required in order to ensure adequate yield. In conventional processing, the circuitry which comprises the sensing elements and their interconnections are processed into the wafer prior to the chemical etching of the diaphragm. The thinning process which forms the pressure-sensitive diaphragm requires the use of an anisotropic etchant system which selectively removes silicon along $\langle 111 \rangle$ crystal planes at an angle of 54.7 degrees to the surface. The wafer must be etched through almost to the opposite surface in order to provide a sufficiently flexible diaphragm. This etch angle, along with a required area of non-etched silicon surrounding the diaphragm for ensuring structural integrity, effectively defines the minimum size of the semiconductor die of the sensor assembly 11 which can be achieved from a given starting wafer thickness. These facts have typically limited prior art sensor assemblies to relatively large die sizes that are incompatible with packaging into catheters small and flexible enough to be used in the very small body cavities contemplated by the present invention.

In accordance with one important aspect of the invention, a diaphragm is first etched into a thin wafer (e.g., .003 inches) and thereafter immediately bonded to a thicker silicon wafer (e.g., .008 inches thick) to provide the structural support needed by the first wafer containing the diaphragm in order to prevent shattering of the diaphragm during further processing steps. Subsequent to the bonding of the

two wafers, the other processing steps required to fabricate the electronic circuitry are performed. Processing the two wafers forming the dice separately for certain key operations and then bonding them together prior to the fabrication of the sensing circuitry not only allows a very thin wafer to be utilized for etching of diaphragms, but also allows fabrication of a unique reference pressure venting feature into the surface of the backing wafer prior to bonding the two wafers together. After bonding, the pressure vent communicates ambient pressure to the cavity formed by the diaphragm through the side of the sensor assembly instead of through the bottom of an amorphous backing structure, as is typical of prior art sensors. This feature is advantageous for sensor assemblies designed to be incorporated into small packages, such as catheters.

Turning to the fabrication of the sensor assembly according to the invention, FIG. 5 illustrates a flow diagram of the important process steps. As a first step (Step One in FIG. 5) a silicon wafer is selected; for example, a two-inch diameter, p-type <100> silicon wafer, 10 ohm-centimeter resistivity, $.003 \pm 0.1$ inches thickness, polished both sides. As a second step (Step Two), an epitaxial (epi) layer of silicon is grown of opposite doping type to the wafer, so that a p-n junction is formed by applying proper bias. The thickness of the epi layer determines the final thickness of the pressure sensitive diaphragm in the completed sensor. An example of a specification for the epi layer which complements the foregoing example for the device wafer is 3.0 ± 0.2 microns, n-type doping, 10 ohm-centimeter.

In Step Three of the flow diagram, a pattern for diaphragms and target holes is placed on the device wafer. Diaphragm geometries may be square or rectangular, and the population density on the wafer may be varied. In accordance with another important aspect of the invention, the target holes provide for fabrication of economical sensors by allowing alignment of sensor features without the use of expensive special purpose equipment. Referring to FIG. 6, there are two target areas 63 and 65 on the device wafer 67 located opposite each other at the periphery outside the diaphragm patterned area 69. Each target area contains two types of targets. One set of targets 71, consisting of one type from each target area 63 and 65 of the wafer 67, is used to align the device and backing wafers during the wafer-wafer bonding process step. This alignment is necessary because V-shaped grooves or channels in the backing wafer must pass through the center of the closed cavities formed by the diaphragms when the wafers are bonded.

A second set of targets 73 provides alignment of successive semiconductor layers to the diaphragms of the device wafer 67 during the fabrication of transduction devices. Such alignment is typically carried out in conventional processing by the use of a double-side optical or infrared mask aligner which allows for the simultaneous viewing of features on both sides of a wafer. This equipment is very expensive and can typically be justified only for those applications in which large quantities of wafers are to be processed on a routine basis.

Typical target patterns of the present invention are squares of dimension 250 x 250 microns for the wafer alignment step (targets 71) and 160 x 160

microns for the layer alignment steps (targets 73), although other sizes and geometries could be used. Both sets of the targets 71 and 73 are patterned along with the diaphragm patterns. During the etching of the diaphragms in the silicon wafer, the target patterns are also etched. Unlike the diaphragms, however, the targets are etched completely through the silicon wafer 67 and appear on the epi side as perfectly square openings. During wafer-to-wafer bonding described hereinafter, the larger openings formed by the first set of targets 71 are used to view directly, with a standard optical microscope, the V-shaped grooves of the backing wafer placed underneath. After the wafers are bonded, the smaller openings visible from the epi surface and formed by the second set of targets 73 are used along with a standard mask alignment system to orient subsequent mask patterns for the circuit fabrication as discussed hereinafter. Each pattern mask contains very fine (e.g., two micron wide) alignment reticles (cross-hairs) which may be positioned through the corners of these smaller openings. With this method, alignment accuracies comparable to that of a double-side optical or infrared aligner can be realized.

After the patterns for the targets and diaphragm have been formed, the epi surface of the device wafer 67 is covered with a sputtered thin film of aluminum in Step Four of FIG. 5 for use as an electrode contact surface during the etch process. Other metals compatible with the process line, such as gold, could also be utilized.

In Step Five of FIG. 5, the device wafer 67 is subjected to the process of selective chemical etching to form small three dimensional structures defining the targets and diaphragms, a conventional

process termed "micromachining" in the art. This process is used typically to provide thin and therefore flexible diaphragm structures for sensor devices, and it is important since the performance of silicon pressure sensors depends upon control over the etched thickness of the diaphragm. Numerous techniques to control the thickness of the diaphragm exist in the prior art; for example, timed etch, boron etch stop, infrared transmission, etc. One of the best available techniques, termed "electrochemical etch stop," is well described. For example, see T.N. Jackson, M.A. Tischler, and K.D. Wise, IEEE Electron Device Letters, EDL-2, 44-46, 1981.

The technique of "electrochemical etch stop" is conventionally described for etching diaphragms from 10-30 microns or more in thickness. For the present application, however, a diaphragm thickness of three microns is required, which to applicants' knowledge has not been previously reported. To achieve such a thin diaphragm, the silicon wafer 67 is placed into a machined stainless steel fixture, which provides mechanical support to the .003 inches thick wafer. The surface on which the wafer 67 lies also serves as a disk electrode for applying the proper electrical bias to the epi (metallized) side. A silicone rubber seal (not shown) covers the electrical contact side of the wafer and isolates the opposite side of the wafer containing the diaphragm pattern (to be etched) from the electrical contact side. Failure to maintain an absolute fluid seal over the electrical contact side results in premature passivation of the silicon wafer with consequent poor diaphragm formation. Several chemical etchant systems could be used; for example, a solution of hydrazine/water

(e.g., 50/50 by volume). From the foregoing discussion, those skilled in the art of semiconductor fabrication will readily appreciate that the fixture and seal for the foregoing etch process are conventional and their precise design a routine task.

The reaction is carried out in a reflux system at or near the boiling point of the etchant (i.e., 119°C for 50/50 hydrazine/water). Positive electrical bias is supplied to the metallized surface of the wafer via the fixture and a reference platinum electrode is located in the etch bath. This allows the p-n junction formed at the interface between the n-type epi layer and the p-type wafer to be maintained in a reverse bias condition. The bias is adjusted so that a current of three to four milliamperes flows while etching proceeds. For a discussion of bias parameters, see R.L. Gealer, H.K. Karsten, and S.M. Ward, J. Electrochemical Society, 135, no. 5, 1180-11183, 1988. After etching begins, it will proceed through non-passivated silicon p-type material until there is no more p-type material remaining (i.e., the epi surface is reached). When the epi surface is exposed, a large increase in current will occur, followed by a rapid decrease in current as the epi surface becomes passivated.

During the etching of the diaphragm, the two sets of targets are also etched through the wafer and halted at the epi surface. To etch the targets through the epi surface, precautions must be taken to protect the diaphragms from further etching. This can be accomplished by replacing the top half of the etch fixture with a silicone seal (not shown) of conventional design which protects the diaphragm surface area of the wafer from the etchant but

exposes the target areas. A second immersion of the wafer into the etchant without bias for a brief period etches the three micron epi layer completely, resulting in clean square targets formed in the top surface of the wafer.

Using conventional processing techniques, the thin metal film applied to the wafer in Step Four is removed in Step Six. In Step Seven, the etched surface of the device wafer is prepared for the bonding process of Step 12, as disclosed, for example, in M. Shimbo, K. Furukawa, K. Fukuda, and K. Tanzawa, J. Appl. Phys., 60(8), 2987-2989, 1986. For proper preparation, the wafer surfaces to be bonded must be thoroughly cleaned and treated to form a hydrophilic layer.

Turning to the preparation of the backing wafer starting at Step Eight in FIG. 5, a representative specification for a silicon starting material for the backing wafer is, for example, a two-inch diameter, p-type <100> silicon wafer, having 10 ohm-centimeter resistivity and $.008 \pm 0.3$ inch thickness and being polished on both sides.

In Step Nine of FIG. 5, patterns for channels in the form of V-shaped grooves are placed on the backing wafer. Each of the V-shaped grooves provides a bore 31 of the sensor assembly 1 (FIGS. 1-3). Each bore 31 functions to communicate a reference pressure through the side of the wafer and to the cavity formed from the diaphragm and closed by the wafer-to-wafer bonding. FIG. 7 shows a backing wafer 75 with V-shaped grooves 31 etched into its surface prior to the wafer bonding step. The grooves 31 extend the full length of wafer 75 and the spacing between grooves corresponds to the center-to-center spacing of the corresponding diaphragm pattern on the device wafer 67. Although applicants

presently form the V-shaped grooves 31 by using an anisotropic etchant which self-stops at the intersection of $\langle 111 \rangle$ planes, it should be understood that such a groove need not necessarily be V-shaped. Other processes for forming the grooves may provide different profile shapes; for example, the grooves could be formed by a wafer dicing saw.

In the present invention, as an example, each V-groove pattern is 100 microns wide, resulting in a self-stopping etch depth of about 70 microns in Step 10. The etch process is conventional; for example, potassium hydroxide, self stopping at the intersection of $\langle 111 \rangle$ planes. Prior to bonding with the device wafer 67, the backing wafer 75 is prepared for the bonding process in the same manner as defined in Step Seven for the device wafer.

At some point in the fabrication of every semiconductor pressure sensor, the sensor must be attached to a backing material to provide structural support. Such backing support inevitably leads to degraded sensor performance over a given temperature span of operation due to mismatches of thermal expansion coefficients inherent to different materials which cause stresses in the sensor structure. In the prior art, the backing material is typically glass, or, preferably, another silicon wafer utilizing a bonding agent, such as a layer of silicon dioxide, followed by an annealing treatment. Direct silicon-to-silicon bonding is considered most advantageous since no third material is present. In Step 12 of the present invention, such a direct silicon-to-silicon bond is achieved. A technique similar to that referenced in Step Seven is utilized to effect the desired bonding and is considered conventional.

In connection with Step 12, FIG. 8 is a side view of the device and backing wafers 67 and 75, respectively, showing etched targets 71 and 73, diaphragms 25, and V-shaped grooves 31 in proper relative alignment. Proper alignment of the wafers 67 and 75 during fabrication centers the V-shaped grooves 31 in the cavities formed by the diaphragms. Preferably, an optical microscope is employed to directly view the backing wafer 75 through the holes of the targets 17. The backing wafer 75 is positioned so that V-grooves 31 are directly under the targets 71 as suggested by the alignment of the wafers in FIG. 8.

In Step 13, the piezoresistor pattern is defined on the epi surface, utilizing the second set of target patterns formed in Step Five. Subsequently, the piezoresistors R_1 - R_3 are formed via conventional ion implantation equipment and driven in by heat treatment. The ion dose delivered and the drive-in recipe are considered conventional, with special consideration, as discussed in a later paragraph, on their contribution to temperature compensation. As is known in the art, any set of stated dose parameters, if defined for a given set of equipment, must be experimentally verified if utilized on other equipment.

In Step 14, the P+ layer which forms the electrical connections to the piezoresistors R_1 - R_4 is patterned, implanted, and annealed, all by conventional processing methods. In Step 15, the contact openings are formed which are necessary to allow connection of the P+ layer to the thin film aluminum tracks of Step 16. As with Step 14, this is conventional processing methodology required of any integrated circuit process.

In Step 16, the metallization pattern is defined, deposited and etched. This pattern includes resistor interconnects for piezoresistors R_1 - R_4 , electrical contact pads for bonding the wires, and the trim network 61. The process steps are considered conventional. The choice of metal and the thickness of deposition have an effect on the overall temperature compensation achieved on-chip, and are further discussed in a later paragraph.

The process step in Step 17 is conventional and includes the provision of a passivation layer over the surface of the device wafer 67 for environmental protection, as well as subsequent opening of windows over the bonding pads. After all processing is complete, the bonded wafers 67 and 75 are sawn into individual sensor die by a conventional wafer dicing process in step 18.

As previously mentioned, the foregoing Steps 13-17 employ the targets 73 in conjunction with a standard mask alignment system to orient the various patterns on the device wafer 67. The targets 73 ensure the proper placement of the fabricated circuit elements relative to the pattern 69 of diaphragms (FIG. 6) on the device wafer 67.

FIG. 9 is a magnified perspective view of a sensor die 81 sawn from the bonded wafers of FIG. 8, showing the sensor die and its component parts. V-shaped groove 31 of backing die 81a is centered in the cavity of diaphragm 25 of the device die 81b. Other features include contact pads 83, the trim network 61, and trim pads 85. FIG. 10 shows the completed sensor die with interconnects 87 for forming a Wheatstone bridge network from the piezoresistors R_1 - R_4 . Fusible links 89 function to allow portions of the trim network 61 to be selectively

added to the bridge circuit formed by the piezo-resistors R_1 - R_4 . Links 89 may be selectively removed by application of a suitable electrical current between two adjacent trim pads 85.

Referring to the schematic diagram of the sensor circuit in FIG. 11, excitation source 53a and meter 53b of the standard monitoring equipment 53 of FIG. 4 are connected to the the sensor circuit formed by the sensor die 81. Piezoresistors R_1 , R_2 , and R_4 , nominally the same value, and piezoresistor R_3 , chosen to be slightly higher in value, form a full Wheatstone bridge and are physically located upon the diaphragm 25 as illustrated in FIG. 10. As the diaphragm 25 is stressed, the resistors R_1 - R_4 change value due to the piezoresistive effect, resulting in a bridge imbalance detected by meter 53b. Variations in the values of the unstressed piezoresistors R_1 - R_4 due to normal fabrication process tolerances will generally result in an imbalance at zero pressure. In this case, the trim network 61 can be utilized to increase the value of resistor R_4 in incremental steps of resistance r_0 until balance is achieved. Adjustment of the effective resistance provided by the trim network 61 is made by removing combinations of shorting links 89 by passing electrical current through the links via pads 85. In addition, since piezoresistor R_3 is fabricated to be larger in value than the other resistors R_1 , R_2 , and R_4 , resulting in a nominal non-zero voltage at zero relative pressure, the trim network 61 can be utilized to remove both positive and negative imbalances.

To provide a stable output signal which is reliable over a full range of expected temperatures, two different but related phenomenon must be considered. First, as is well known in the art, the

value of the resistance for each piezoresistor R_1 - R_4 implanted in the wafer 67 is a function of the ambient temperature. Second, as is also well known in the art, the value of the piezoresistive coefficient is a function of the ambient temperature. The first phenomenon is quantified as a temperature coefficient of resistance (TCR), and the second is quantified as a temperature coefficient of the piezoresistive coefficient (TCPI). In practice, the TCR affects the zero offset of the output signal from the sensor, and the TCPI affects the sensitivity of the piezoresistors. An uncompensated change in the TCPI will cause a change in the magnitude of the output signal from the piezoresistive bridge network, assuming a static pressure differential across the diaphragm 25. Typically, the sensitivity of the piezoresistive bridge network decreases with increasing temperature and the nominal value of the resistance of the network increases.

Typical mechanisms for compensating for the change in sensitivity caused by the TCPI include the use of constant current excitation with controlled TCR values to compensate for the loss of sensitivity. J. Bryzek, "Approaching Performance Limits In Silicon Piezoresistive Pressure Sensors," Sensors and Actuators, 4 (1983); M. Poppinger, "Silicon Diaphragm Pressure Sensors," Solid State Devices 1985, Elsevier Science Publishers B.V., 1986. As an alternative to the use of constant current excitation, external active circuits have been used. Samaun, K.D. Wise, and J.B. Angell, "An IC Piezoresistive Pressure Sensor for Biomedical Instrumentation," IEEE Transactions On Biomedical Engineering, Volume BME-20, No. 2, March 1973. Because the sensor assembly 11 is intended to be

compatible with existing blood pressure amplifiers, the use of constant current excitation is not an acceptable mechanism for temperature compensation. Furthermore, external active circuits are expensive and are not in keeping with the object of the invention to provide a low cost device.

In accordance with another important aspect of the invention, the TCPI-dependent effects on the sensitivity of the sensor assembly 11 may be compensated for with the use of the external compensation network 57 and an on-chip TCR value which complements the value of the on-chip TCPI. Specifically, the piezoresistors R_1 - R_4 comprising the bridge network are fabricated to have TCR and TCPI values which complement each other in the following manner: As the piezoresistive response of the piezoresistors R_1 - R_4 changes in response to the temperature changes, the effective voltage applied across the bridge network is increased in a manner that results in a net zero change in the magnitude of the output signal. By way of illustration, the compensation network 57 composed of passive resistor elements and the network of piezoresistors R_1 - R_4 can be modeled as a resistive ladder comprising in series a first external resistor R_1 , the network of piezoresistors R_B and a second external resistor R_2 . Using Ohm's law, the voltage V_E across the bridge network equals,

$$V_E = \frac{R_B}{R_1 + R_2 + R_B} \times V_0 \quad (1)$$

where V_0 is the voltage applied from conventional monitoring equipment. The value of the bridge resistance R_B is a function of the TCR. From equation (1), it is readily apparent that the value

of the voltage V_E is related to the value of the bridge resistance R_B and, therefore, the TCR effects the value of V_E . When correctly calibrated, the sensor assembly 11 should provide five microvolts per volt excitation for every mmHg of pressure across the diaphragm 25. With a change of temperature, the sensor assembly 11 may provide, for example, only 4.5 $\mu\text{V/V/mmHg}$. However, the same temperature change causing the sensitivity of the piezoresistors R_1 - R_4 to decrease also causes the resistance R_B of the bridge network to increase. Because the response of the piezoresistive bridge network is not only a function of the TCPI, but also of the applied voltage V_E across the bridge, the proper selection of the TCR of the bridge can cause a change in V_E which will offset the effect of the TCPI.

As fabricated, the sensor assembly 11 has a theoretical piezoresistive response of greater than the five $\mu\text{V/V/mmHG}$ standard used by conventional monitoring equipment; therefore, the compensation network 57 connected in series with the piezoresistive bridge network is also useful in attenuating the sensitivity. The resistors of the compensation network 57 are provided off-chip in accordance with the invention and have several advantages: namely, they allow sensitivity calibration after final assembly; they simplify IC fabrication; and they reduce on-chip power dissipation. These off-chip resistors also cooperate with the TCR of the piezoresistive bridge network to provide temperature compensation for the effects of the TCPI.

The value for these off-chip resistors (hereinafter called "Rspan" resistors) to properly scale the sensitivity of the sensor is easily calculated. By

selecting the value of the TCR for the off-chip resistors R_{span} to be zero, an equation may be derived to select a TCR value for the piezoresistors R_1 - R_4 which corrects for the change of sensitivity as a function of temperature due to TCPI.

$$TCR = [2R_{span}/((2R_{span}+R_B)(1+TCPI)-R_{span})] - 1 \quad (2)$$

By choosing a fabrication process which results in a TCR as close as possible to the value calculated by Equation (2), a device is produced having an acceptable temperature compensated sensitivity.

For a given fabrication process, the TCR of p-type resistors R_1 - R_4 in the piezoresistive bridge may be approximated from available equations. The sheet resistance (R_s) is a function of acceptor dose and hole mobility. The change of the sheet resistance (R_s) caused by a change of temperature is due to the temperature dependence of hole mobility, and equations approximating hole mobility as a function of acceptor ion concentration (controlled in the fabrication process) and temperature are known and published in, for example, N.D. Arora, J.R. Hauser, and D.J. Roulston, "Electron and Hole Mobilities in Silicon as a Function of Concentration and Temperature," IEEE Transactions on Electron Devices, Volume ED-29, No. 2, February 1983.

The temperature coefficient of resistance (TCR) for a given fabrication process can be predicted by calculating the sheet resistance (R_s) at temperatures T and $T+1$:

$$TCR = (R_s(T+1) - R_s(T))/R_s(T) \quad (3)$$

With the calculated values of the sheet resistance (R_s) as a starting point, the TCR is experimentally verified for a given fabrication process.

As is the case with TCR approximations, the value of TCPI for a given fabrication process may be mathematically approximated by available equations such as, for example, Ki Won Lee, "Modeling and Simulation of Solid-State Pressure Sensors," Ph.D. Dissertation, University of Michigan, Ann Arbor, 1982. The calculated value of TCPI may be used in Equation (2) to calculate the desired value of TCR. Actual experimental verification may be required to confirm expected results.

In addition to choosing the appropriate doping level to achieve complementary TCR and TCPI values, the preferred doping level also provides a piezoresistive coefficient that results in a high pressure sensitivity (i.e., sensitivity compatible with standard equipment) while maintaining minimum sensitivity of the piezoresistive coefficient to small variances in the doping levels which result from normal fabrication tolerances. Finding the preferred doping level is a technique which is well known in the art of fabrication processes.

Normal variations in the fabrication process also result in slightly different nominal resistance values for the piezoresistors R_1 - R_4 , thereby causing an offset of the output voltage from the piezoresistive bridge network. As previously mentioned, to provide the ability to trim the zero-pressure offset voltage, one of the piezoresistors R_1 - R_4 is deliberately fabricated to have a slightly greater nominal resistance than the others. In the illustrated embodiment, this piezoresistor is R_3 . The piezoresistor R_4 is in series with a thin film

resistance of the trim network 61. The resistances of the thin film may be selectively inserted so as to cause the series value of R_4 and the trim network 61 to approach the value of R_3 .

The effective resistance of the trim network 61 is adjusted by opening fusible links 89 with either a pulse of current or a laser. The network 61 forms a resistive ladder configuration (see FIG. 11) wherein the links 89 shunt resistive elements r_0 . As links 89 are selectively opened, the resistance of the trim network 61 increases.

The trim network 61 is fabricated from an aluminum alloy containing one percent silicon. This material is commonly used in IC technology for electrical pads and connecting tracks, and is characterized by a TCR of approximately that calculated by Equation (2). In this regard, the TCR of the thin film network 61 matches that of the piezoresistors R_1 - R_4 and consequently the thin film network does not contribute significantly to thermally induced offset errors.

Other design and fabrication considerations for the sensor assembly 11 are well known in the art. For example, because the piezoresistors R_1 - R_4 are fabricated in close proximity to one another, their resistances track each other well. Because the sensor assembly 11 operates in an environment of a limited temperature range (i.e., 15 to 45°C.), junction leakage current is not a problem. Also, thermally-induced stress at the junctions between silicon of the wafer 67 and the silicon dioxide of the piezoresistors R_1 - R_4 is minimized by keeping the silicon dioxide layer thin.

An alternative embodiment of the invention is illustrated in FIG. 12 wherein each of two bonded

dies 91 and 93 serves both a device and a backing function. In this case, a single assembly 95 contains two diaphragms 97 and their associated V-grooves 99. Diaphragm 97 of one die 91 defines a first sensor and a second diaphragm 97 of die 93 defines a second sensor on the opposite surface of the assembly 95. Such an arrangement would be useful in fabrication of a special purpose catheter designed to measure pressure gradients along a vessel length, such as across a stenosis or valve. Such an assembly could be located in one lumen of a double lumen catheter, with one sensor facing directly into the vessel lumen through a suitable opening of the outer catheter wall and the other sensor facing the second catheter lumen through an opening in the center wall. This second sensor measures pressure as transmitted through the fluid column existing between the tip of the catheter and the site of placement of the sensor within the catheter. The pressure gradient existing between the tip of the catheter and the location of the sensor assembly is recorded as the difference between the outputs of the two sensors.

From the foregoing, it will be appreciated that a miniaturized pressure sensor assembly 11 is provided which is adapted for placement at the tip of a conventional catheter such as the catheters shown in FIGS. 2a-2c and FIGS. 3a-3c. By fabricating the sensor assembly 11 in accordance with the invention, a unique sensor structure is provided which allows miniaturization to an extent previously unknown in the art. By utilizing targets formed in the wafers from which the assembly 11 is fabricated, the fabrication process can be completed without the need for expensive alignment equipment, thereby allowing

the sensor assembly to be manufactured relatively inexpensively. Furthermore, the temperature compensation techniques employed in connection with the pressure sensor assembly 11 allow the device to perform with high reliability over the temperature range of its expected environment. Embodiments of the invention other than in the pressure sensor assembly 11 shown in FIGS. 1-11 are suggested by the alternative embodiment of the invention shown in FIG. 12. Those skilled in the art of pressure sensing apparatus for recording physiological pressure will appreciate that still other alternative embodiments for the invention are possible.

We claim:

1. A pressure sensitive transducer device adapted to be enclosed within the tip of a catheter or the like for insertion into a small cavity, said transducer comprises:

a device die composed from a thin wafer material of uniform thickness, said device die having a cavity opening to a first side of said device die and forming a diaphragm etched out of said device die, wherein said diaphragm contains piezoresistive elements which change their characteristic resistances in response to very slight changes in stress on the diaphragm produced by a pressure differential across said diaphragm;

a backing die composed of a crystalline material, said backing die having a first surface bonded to said first surface of said device die so as to close said cavity between said backing and said device dies;

a groove in said first side of said backing die for providing a vent for said closed cavity to a reference pressure source;

whereby the resistive changes in said piezoresistive elements of said diaphragm are monitored to produce a signal which represents the differential pressure across said diaphragm.

2. A pressure sensitive transducer device according to claim 1 wherein said piezoresistive elements form a bridge network which includes a resistive trim network for adjusting the nominal resistive parameters of said bridge network.

3. A pressure sensitive transducer device according to claim 2 wherein said resistive trim network comprises a thin film resistor shunted by series connected fusible links.

4. A pressure sensitive transducer device according to claim 2 wherein the temperature coefficient of resistance (TCR) of said resistive trim network is substantially the same as the temperature coefficient of resistance (TCR) of said piezoresistive elements.

5. A method of manufacturing pressure sensitive transducer devices comprising the steps of:

processing a first thin wafer of crystalline structure to form a pattern of diaphragms comprising a plurality of rows;

processing a second thin wafer of crystalline structure to include a pattern of small channels formed along a first surface of said second thin wafer;

bonding said first and second thin wafers such that each of said channels of said second thin wafer is aligned with one row of said pattern of diaphragms of said first thin wafer and in communication with a closed cavity formed by each of said diaphragms in said one row;

processing the bonded first and second thin wafers to form electrical circuits to perform pressure transduction in association with said diaphragms; and

cutting the bonded first and second wafers into a plurality of individual pressure sensitive transducer devices.

6. A method as set forth in claim 5 wherein the step of processing said first thin wafer includes etching target holes through said first thin wafer and the step of bonding said first and second thin wafers includes the step of aligning said channels of said second thin wafer and said pattern of diaphragms of said first thin wafer by referencing said target holes to said channels.

7. A method as set forth in claim 5 wherein the step of processing said first thin wafer includes etching target holes through said first thin wafer and the step of processing the bonded first and second thin wafers includes placing pressure transducing devices on said bonded first and second thin wafers by referencing the fabrication of said devices to said target holes.

8. A process of fabricating semiconductor devices comprising the steps of:

processing a first wafer of crystalline structure to create a feature of said semiconductor device in said first wafer and a set of holes in the perimeter of said first wafer;

processing a second wafer of crystalline structure to create a feature of said semiconductor device in said second wafer;

aligning said first and second wafers for bonding by using said at least two holes in said first wafer as a guide so said features of said semiconductor devices of said first and second wafers have a predetermined spatial relationship when said first and second wafers are bonded;

bonding said first and second wafers; and

processing said bonded first and second wafers to provide a plurality of semiconductor devices.

9. A process as set forth in claim 8 wherein said processing said bonded first and second wafers includes the step of using said set of holes in said perimeter of said first wafer as a reference for aligning the fabrication of semiconductor junctions and the placement of conductive strips.

10. A process as set forth in claim 8 wherein the step of processing said first wafer includes growing an epitaxial layer on said first wafer and etching said first wafer to said epitaxial layer in a manner that results in said feature being a plurality of cavities forming diaphragms.

11. A process as set forth in claim 8 wherein said step of processing said second wafer includes the step of forming a plurality of parallel grooves in said second wafer.

12. A process as set forth in claim 9 wherein the step of fabricating semiconductor junctions and conductive strips includes the step of matching TCR and TCPI values to provide a sensitivity of said semiconductor devices which is substantially independent of temperature for the expected temperature range of the intended environment for the semiconductor device.

13. A process as set forth in claim 8 wherein said processing of said bonded first and second wafers includes substantially all the fabrication

involving the doping of said first or second wafers and placement of conductive or resistive metallic strips onto the surface of said first or second wafers in order to realize said semiconductor device.

14. A process of fabricating semiconductor devices comprising the steps of:

processing a first wafer of crystalline structure to create a feature in a first side of said first wafer and a first set of holes in the perimeter of said first wafer having a known spatial relationship to said feature;

fabricating a circuit on a second side of said first wafer and precisely locating the elements of said circuit relative to said feature by using said set of holes as a reference so as to provide a plurality of said semiconductor devices.

15. A process as set forth in claim 14 including the steps of:

processing a second wafer of crystalline structure to create a feature in a first side of said second wafer; and

bonding said first side of said first and second wafers before fabricating said circuit on said second side of said first wafer.

16. A process as set forth in claim 15 wherein precise spatial relationships are maintained between said features of said first and second wafers during bonding of said first and second wafers by using said set of holes as a reference for aligning said first and second wafers.

17. A process as set forth in claim 14 wherein said step of fabricating a circuit on said second side of said first wafer includes the step of providing matching TCR and TPCI values for said elements of said circuit such that the sensitivity of each semiconductor device is substantially independent of temperature for the expected temperature range of the device's intended environment.

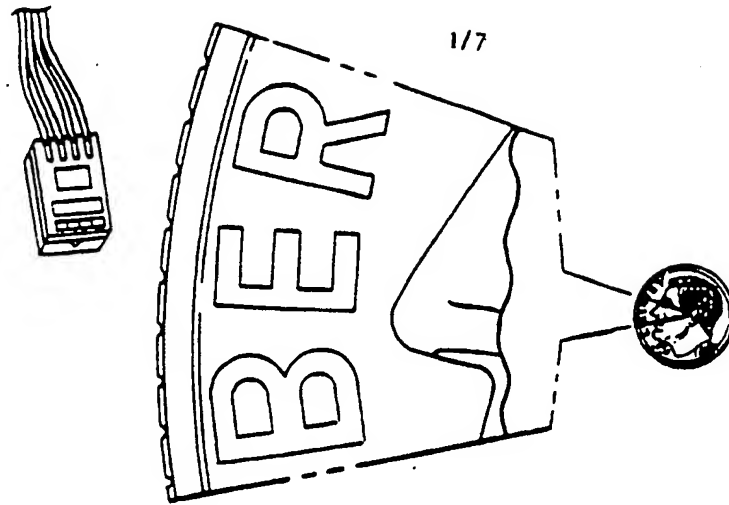


FIG. 1

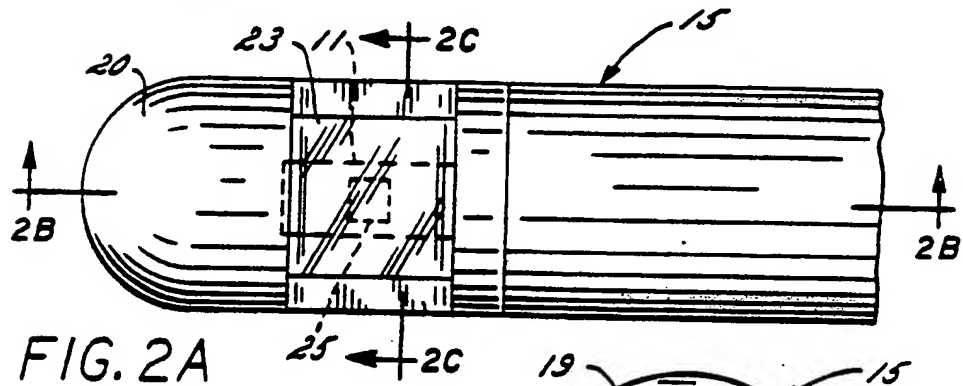


FIG. 2A

FIG. 2C

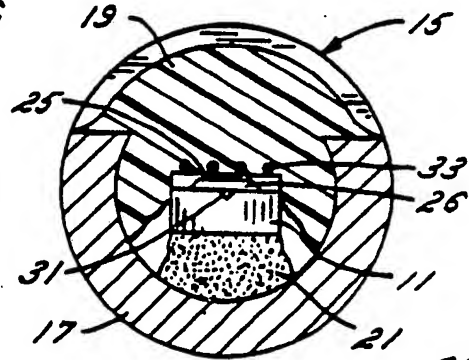
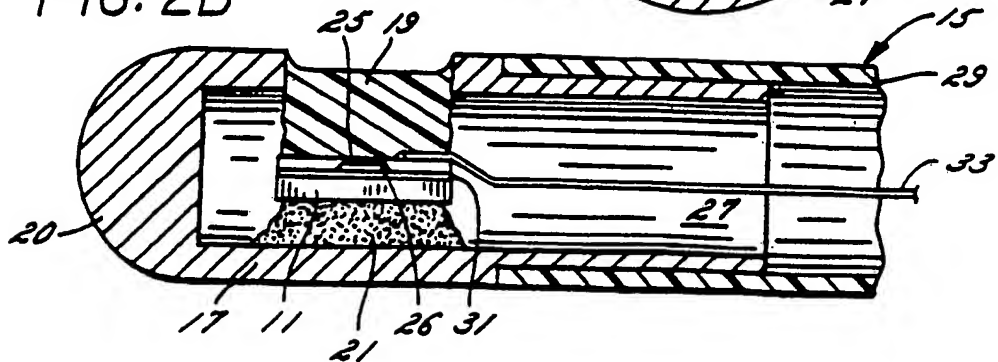


FIG. 2B



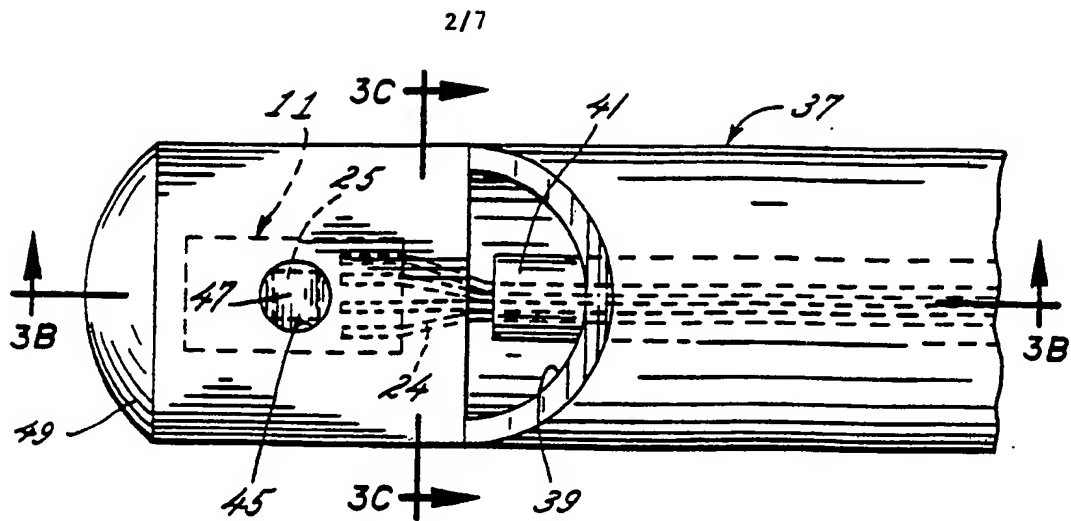


FIG. 3A

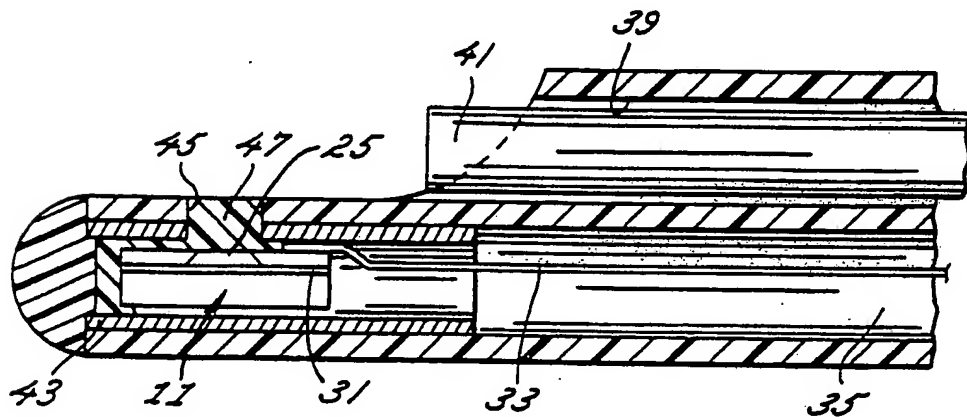


FIG. 3B

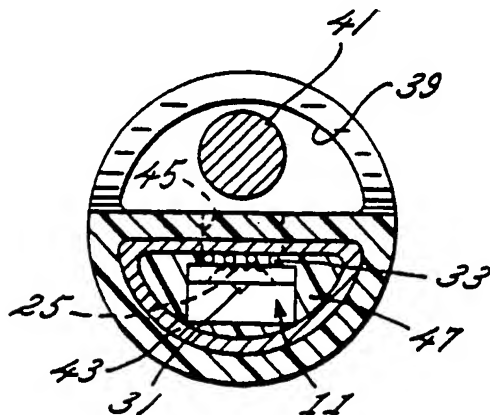


FIG. 3C

3/7

FIG. 4

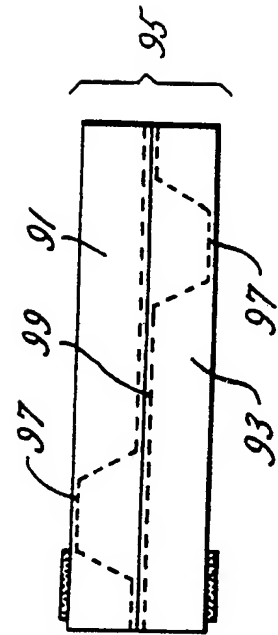
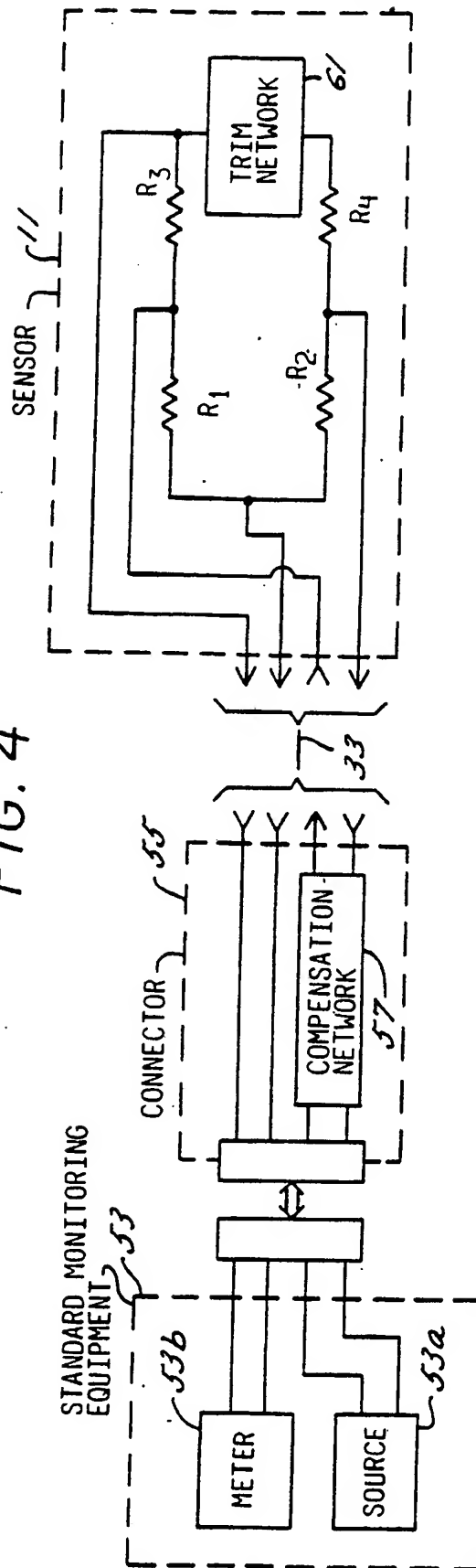


FIG. 12

4/7

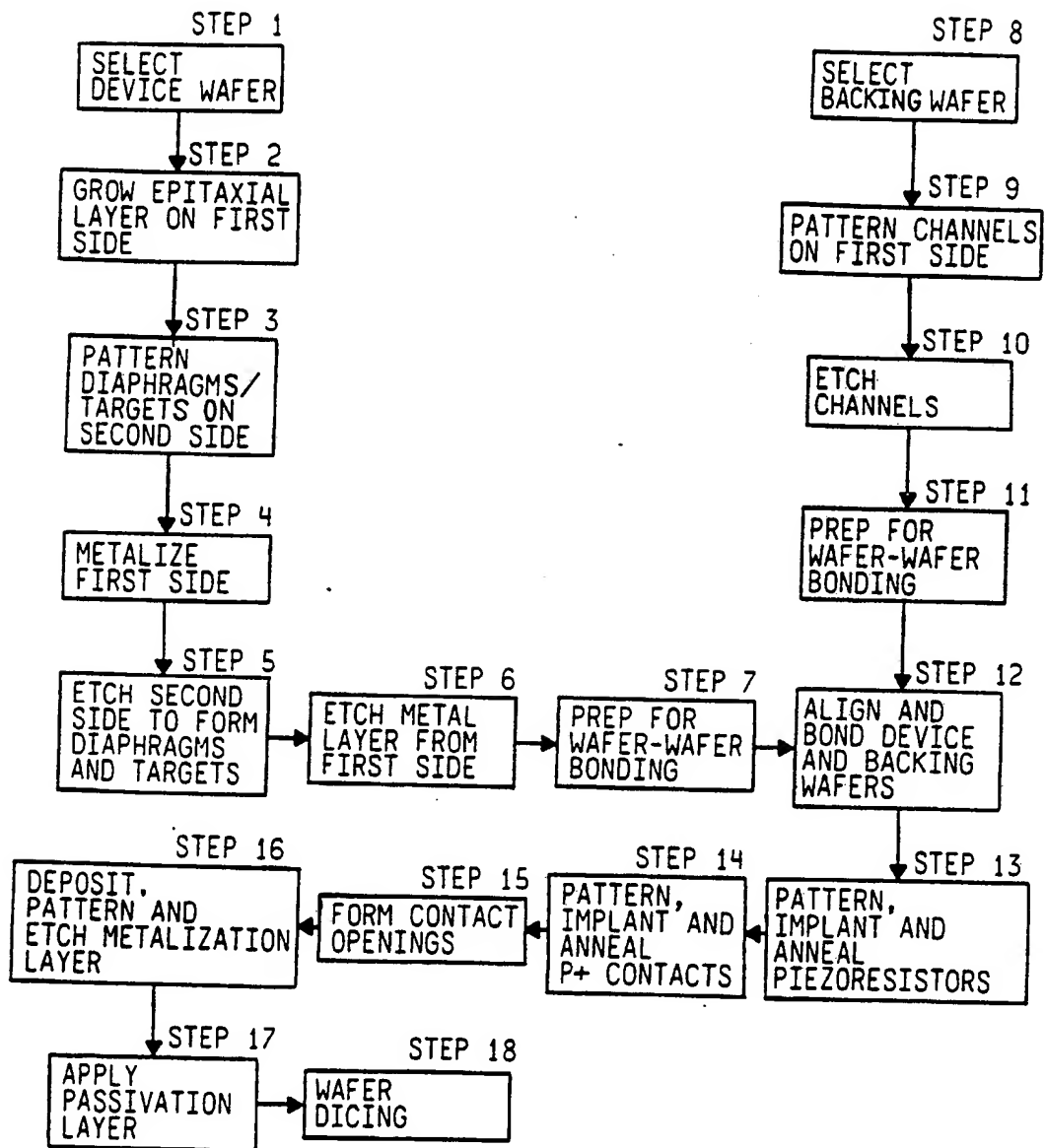


FIG. 5

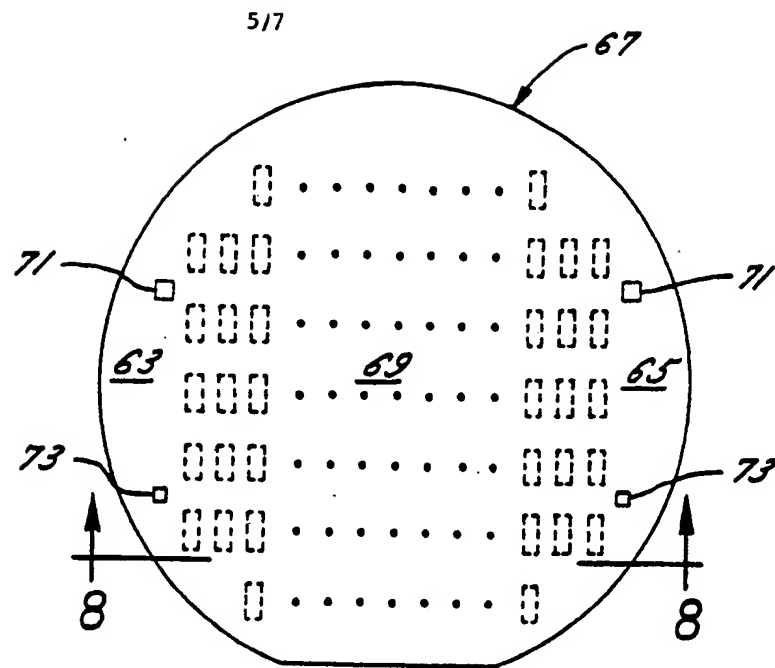


FIG. 6

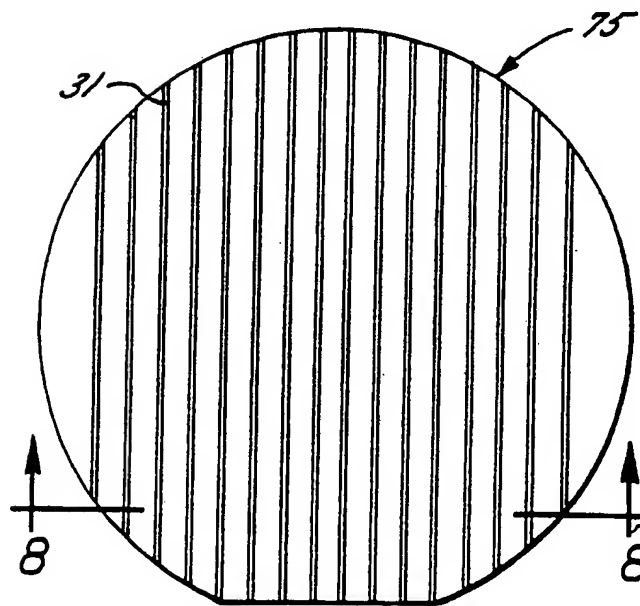


FIG. 7

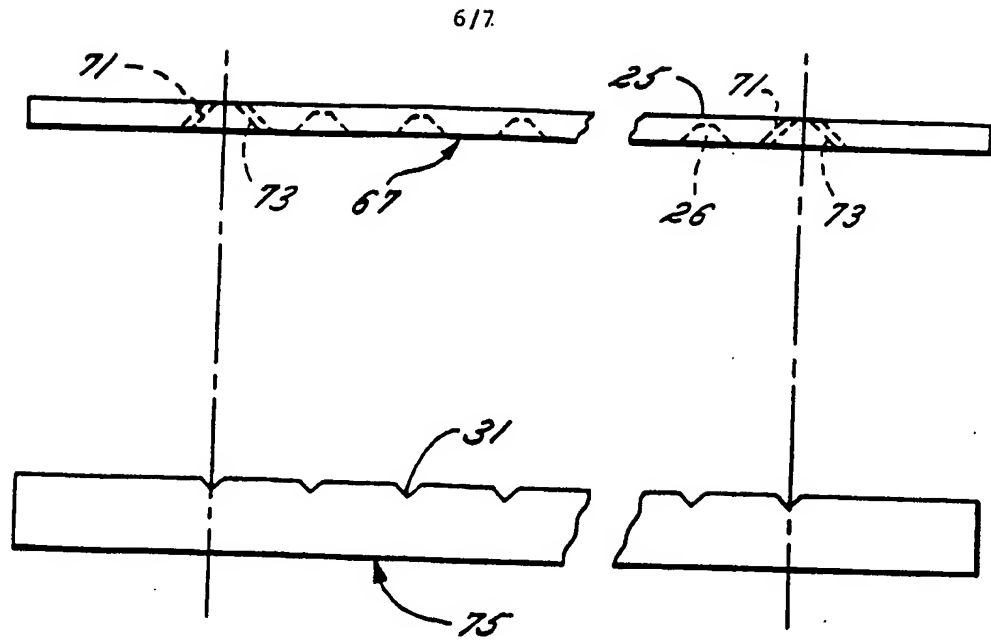


FIG. 8

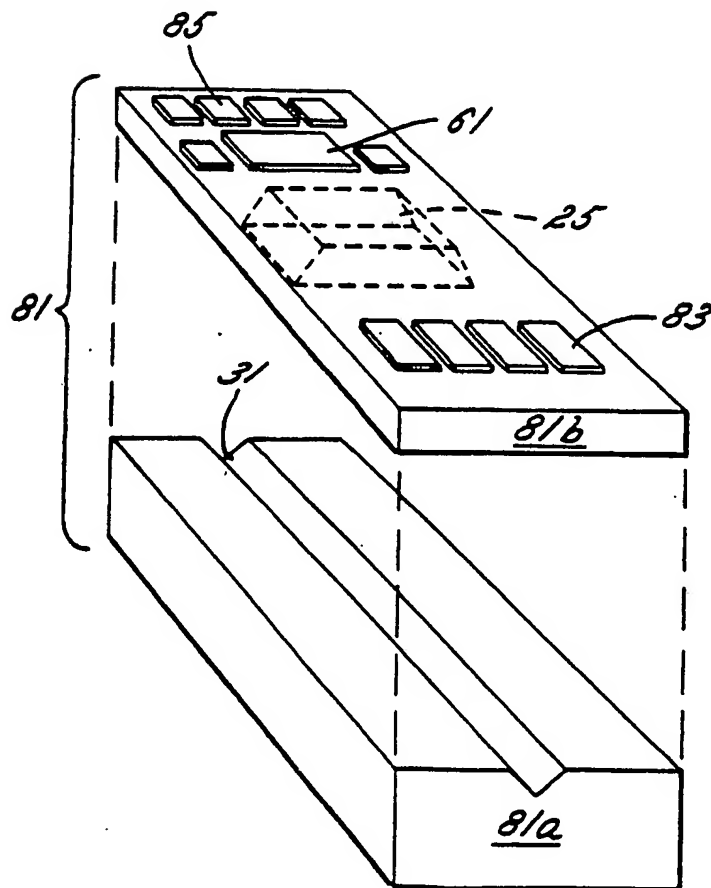


FIG. 9

7/17

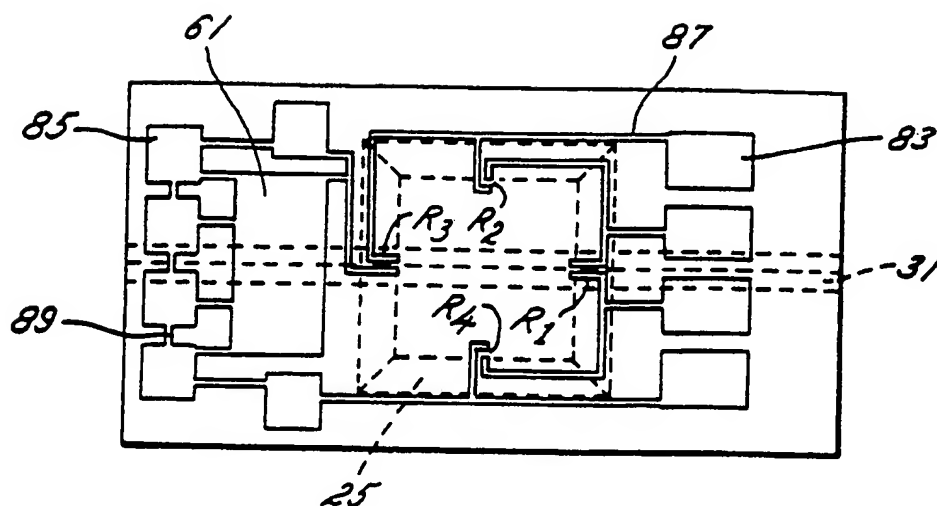


FIG. 10

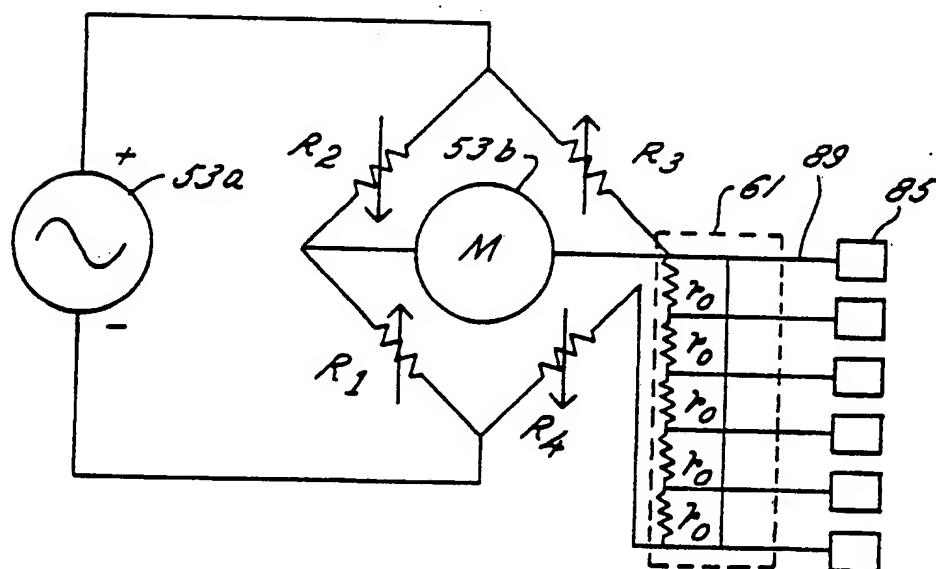


FIG. 11

INTERNATIONAL SEARCH REPORT

International Application No. PCT/US89/05586

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) * According to International Patent Classification (IPC) or to both National Classification and IPC <div style="display: flex; justify-content: space-between;"> IPC(5) A61B 5/0215 U.S. Cl. 128/675,748 29/621.1 </div>																							
II. FIELDS SEARCHED <div style="text-align: center; margin-top: 10px;">Minimum Documentation Searched ⁷</div> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 20%;">Classification System</th> <th>Classification Symbols</th> </tr> <tr> <td style="text-align: center; vertical-align: top;">U.S.</td> <td>128/672,673,674,675,748 73/720,721,726,727,777 29/621.1</td> </tr> </table> <div style="text-align: center; margin-top: 10px;">Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁸</div>			Classification System	Classification Symbols	U.S.	128/672,673,674,675,748 73/720,721,726,727,777 29/621.1																	
Classification System	Classification Symbols																						
U.S.	128/672,673,674,675,748 73/720,721,726,727,777 29/621.1																						
III. DOCUMENTS CONSIDERED TO BE RELEVANT ⁹ <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 10%;">Category *</th> <th style="width: 60%;">Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²</th> <th style="width: 30%;">Relevant to Claim No. ¹³</th> </tr> <tr> <td style="text-align: center;">Y</td> <td>US, A, 4,722,348 (LIGTENBERG) 02 February 1988. See the entire document.</td> <td style="text-align: center;">1-4</td> </tr> <tr> <td style="text-align: center;">Y</td> <td>US, A, 4,766,666 (SUGIYAMA) 30 August 1988. See the entire document.</td> <td style="text-align: center;">1-4</td> </tr> <tr> <td style="text-align: center;">Y</td> <td>1 EEE Transactions on Biomedical Engineering, vol. BME-33, no. 2, (SMITH ET AL.), "Analysis, Design, and Performance of a Capacitive Pressure Sensor 1C".</td> <td style="text-align: center;">2-4</td> </tr> <tr> <td style="text-align: center;">A,P</td> <td>US, A, 4,809,704 (SOGAWA) 07 March 1989. See the entire document.</td> <td style="text-align: center;">1-17</td> </tr> <tr> <td style="text-align: center;">A</td> <td>"Bonding Techniques for Microsensors" Micromachining and Micropackaging of Transducers, (KO) 1985. See the entire document.</td> <td style="text-align: center;">5-17</td> </tr> <tr> <td style="text-align: center;">A</td> <td>Journal of Applied Physiology, "Siticon to Siticon Direct Bonding Method" (SHIMBO) 15 October 1986. See the entire document.</td> <td style="text-align: center;">5-17</td> </tr> </table>			Category *	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³	Y	US, A, 4,722,348 (LIGTENBERG) 02 February 1988. See the entire document.	1-4	Y	US, A, 4,766,666 (SUGIYAMA) 30 August 1988. See the entire document.	1-4	Y	1 EEE Transactions on Biomedical Engineering, vol. BME-33, no. 2, (SMITH ET AL.), "Analysis, Design, and Performance of a Capacitive Pressure Sensor 1C".	2-4	A,P	US, A, 4,809,704 (SOGAWA) 07 March 1989. See the entire document.	1-17	A	"Bonding Techniques for Microsensors" Micromachining and Micropackaging of Transducers, (KO) 1985. See the entire document.	5-17	A	Journal of Applied Physiology, "Siticon to Siticon Direct Bonding Method" (SHIMBO) 15 October 1986. See the entire document.	5-17
Category *	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³																					
Y	US, A, 4,722,348 (LIGTENBERG) 02 February 1988. See the entire document.	1-4																					
Y	US, A, 4,766,666 (SUGIYAMA) 30 August 1988. See the entire document.	1-4																					
Y	1 EEE Transactions on Biomedical Engineering, vol. BME-33, no. 2, (SMITH ET AL.), "Analysis, Design, and Performance of a Capacitive Pressure Sensor 1C".	2-4																					
A,P	US, A, 4,809,704 (SOGAWA) 07 March 1989. See the entire document.	1-17																					
A	"Bonding Techniques for Microsensors" Micromachining and Micropackaging of Transducers, (KO) 1985. See the entire document.	5-17																					
A	Journal of Applied Physiology, "Siticon to Siticon Direct Bonding Method" (SHIMBO) 15 October 1986. See the entire document.	5-17																					
<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>* Special categories of cited documents: ¹⁰</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="width: 45%;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&" document member of the same patent family</p> </div> </div>																							
IV. CERTIFICATION <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; padding: 5px;"> Date of the Actual Completion of the International Search <div style="text-align: center; font-weight: bold;">03 March 1990</div> </td> <td style="width: 50%; padding: 5px;"> Date of Mailing of this International Search Report <div style="text-align: center; font-weight: bold; font-size: 1.2em;">30 MAR 1990</div> </td> </tr> <tr> <td style="padding: 5px;"> International Searching Authority <div style="text-align: center;">ISA/US</div> </td> <td style="padding: 5px;"> Signature of Authorized Officer <div style="text-align: center;">Angela D. Sykes</div> </td> </tr> </table>			Date of the Actual Completion of the International Search <div style="text-align: center; font-weight: bold;">03 March 1990</div>	Date of Mailing of this International Search Report <div style="text-align: center; font-weight: bold; font-size: 1.2em;">30 MAR 1990</div>	International Searching Authority <div style="text-align: center;">ISA/US</div>	Signature of Authorized Officer <div style="text-align: center;">Angela D. Sykes</div>																	
Date of the Actual Completion of the International Search <div style="text-align: center; font-weight: bold;">03 March 1990</div>	Date of Mailing of this International Search Report <div style="text-align: center; font-weight: bold; font-size: 1.2em;">30 MAR 1990</div>																						
International Searching Authority <div style="text-align: center;">ISA/US</div>	Signature of Authorized Officer <div style="text-align: center;">Angela D. Sykes</div>																						